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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/692,310  | 10/22/2003  | Boris Reydel         | 10000-232           | 8560             |
| 757 7590 02/27/2009<br>BRINKS HOFER GILSON & LIONE<br>P.O. BOX 10395<br>CHICAGO, IL 60610 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| WITCZAK, CATHERINE  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3767  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 02/27/2009  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/692,310

**Applicant(s)**

REYDEL ET AL.

**Examiner**

CATHERINE N. WITCZAK

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1, 2, 6-21, 23, 26, 28-38 and 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (US 4,946,440) as modified by Hall.

Hall discloses a flexible introducer member (12), a sleeve (90) having a plurality of apertures (102) with a first body portion attached to the introducer and an eversible second body portion (92) moveable in response to a second member (16) sized for introduction through the introducer member; Hall discloses in column 5, line 60 that the internal passage is the duodenum; Hall discloses in Figure 3 the introducer (12) including a second passageway; Hall disclose in Figure 4 a third member (84) preloaded in the passageway of the second member (16).

Hall discloses the claimed invention but does not disclose expressly the second end of the flexible member being attached within the passageway of the second member. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to attach the second end of the flexible member to the inside of the second member because Applicant has not disclosed that attaching the second end of the flexible member to the inside of the second member provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the second end of the flexible member attached to the outer surface of the second member because it is a matter of obvious design choice as to where to attach – on the outer or inner surface- the second end of

the flexible member. Therefore, it would have been an obvious matter of design choice to modify Hall to obtain the invention as specified in the claims.

2. Claims 1, 3, 4, 5, 22, 23, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al (US 5,389,089) as modified by Bauer et al.

Bauer discloses a flexible introducer member (27) positioned in a protion of an endoscope (63), a polymeric sleeve (45) with a first body portion attached to the introducer and an eversible second body portion moveable in response to a second member (43) sized for introduction through the introducer member.

Bauer discloses the claimed invention but does not disclose expressly the second end of the flexible member being attached within the passageway of the second member. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to attach the second end of the flexible member to the inside of the second member because Applicant has not disclosed that attaching the second end of the flexible member to the inside of the second member provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the second end of the flexible member attached to the outer surface of the second member because it is a matter of obvious design choice as to where to attach – on the outer or inner surface- the second end of the flexible member. Therefore, it would have been an obvious matter of design choice to modify Bauer to obtain the invention as specified in the claims.

3. Claims 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall as modified by Hall.

Hall discloses the claimed invention, expect for disclosing expressly the length of the sleeve being at least 20 cm in length and the introducer and second members comprising catheter having lengths of at least 150 cm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the lengths of the sleeve and catheters because Applicant has not disclosed that these specific dimensions provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a sleeve of at least 20 cm in length and catheters of 150 cm in length because these are ranges commonly used in the art. Therefore, it would have been an obvious matter of design choice to modify Hall to obtain the invention as specified in claims 24, 25, and 27.

#### ***Response to Arguments***

Applicant's arguments filed 11/20/2008 have been fully considered but they are not persuasive. Applicant argues that the decision to attach the first end of the flexible sleeve to the inside of the inner tube and the second end of the flexible sleeve to the inside of the outer tube is not a matter of obvious design choice. Examiner disagrees. Applicant is correct in stating that there is "no requirement that Applicant anticipate every difference between the invention and every prior art reference that an Examiner might conceivable relay upon during prosecution of the application, and then include in the application an explanation of any advantages the invention may provide over those differences." However, this is true only if these differences are ones that the Applicant does not consider to be at the crux of the Applicant's invention. If, as in the present case, the applicant did not provide any teaching as to the importance of where (inside or outside) the sleeve is attached; and b) it is known in the art of eversible sleeve devices to connect sleeves both either the insides or outsides of the inner and outer tubes

– it is the Examiner's position that it is a clear case of obvious design choice to modify the attachment site of the sleeve as rejected above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767